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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,358	01/07/2002	Toshiaki Tagawa	P21620	9232
7055	7590	03/18/2004	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C.			KISHORE, GOLLAMUDI S	
1950 ROLAND CLARKE PLACE			ART UNIT	
RESTON, VA 20191			PAPER NUMBER	
			1615	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/926,358

**Applicant(s)**

TAGAWA ET AL.

**Examiner**

Gollamudi S Kishore, PhD

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1-12-2004. 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The amendment dated is acknowledged.

Claims included in the prosecution are 1-34.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added limitation of 40 mole % has no support in the originally filed application and therefore, deemed to be new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These methods of treatment of cancer claims depend on composition in either claim 1 or claim 10; the parent claims however, do not recite any anti-cancer agents.

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*Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Tagawa (5,264,221).

Tagawa discloses liposomal compositions wherein the liposomes have maleimide residues on the surface. A protein (monoclonal antibody) and residues of a compound having polyalkylene glycol moiety are bonded via respective groups to the maleimide residues. The liposomes encapsulate the anti-cancer drug, adriamycin (note the abstract, col. 2, line 45 through col. 5, line 27 and examples). The mol. percent of the bonded compound as disclosed in the reference on col. 4, lines 59-68 appear to fall within the claimed range. The degree of polymerization of PEG is 20-400 as noted from col. 4, line 20 which corresponds to instant molecular weights.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Tagawa does not teach instant mole percentages of the bonded compound in claim 1 and the amount of the bonded antibody in claim 10. The examiner disagrees and points out to Tagawa's teachings on col. 4, lines 59-68 where according to Tagawa, the thiol modified antibody is between 0.01 mole percent to 20 mole percent. According to applicant's own statement on page 15 of the response, only half of the maleimidated lipid is assumed to be present outside the liposome and

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therefore, the percentages taught by Tagawa on col. 4, correspond to both antibody and the compound loaded with PEG compound.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tagawa cited above.

As pointed out above, Tagawa discloses liposomal compositions wherein the liposomes have maleimide residues on the surface. A protein (monoclonal antibody) and residues of a compound having polyalkylene glycol moiety are bonded via respective groups to the maleimide residues. The liposomes encapsulate the anti-cancer drug, adriamycin (note the abstract, col. 2, line 45 through col. 5, line 27 and examples). Tagawa's does not teach the entire claimed range of the bonded compound and the bonded antibody. However, on col. 4, line 53 et seq., Tagawa teaches the activation of the liposome first, that is introducing excess amount of maleimide groups and then reacting first with the thiol activated antibody and then blocking the remaining maleimide groups on the liposomes with excess amount of thiol modified PEG. From these teachings, it is deemed obvious to one of ordinary skill in the art to manipulate the amounts of the thiol activated antibody, since this amount depends upon the amount of the

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corresponding receptors on/in the host cell and then block the rest of the maleimide groups on the liposomes with the thiol modified PEG. Instant invention therefore, is deemed to be an obvious extension of prior art's teachings.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is (703)  
872-9306.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is 703 308  
1234.



Gollamudi S Kishore, PhD  
Primary Examiner  
Art Unit 1615

GSK